Centers for Medicare & Medicaid Services
Special Open Door Forum
Medicare Imaging Demonstration Project
Moderator: Natalie Highsmith
May 27, 2009
9:30 am ET

Operator: Good morning. My name is David and I will be your conference facilitator today.

At this time, I would like to welcome everyone to the Centers for Medicare and Medicaid Services Special Open Door Forum on the Medicare Imaging Demonstration Project. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. If you would like to ask a question during this time, simply press star then the number 1 on your telephone keypad. If you would like to withdraw your question, press the pound key. Thank you. Ms. Highsmith, you may begin your conference.

Natalie Highsmith: Thank you, David, and good morning to everyone and thank you for joining us for this Special Open Door Forum to solicit stakeholder input for the design and development of the appropriate use of imaging services demonstration.

This demonstration was authorized by Section 135(b) in the Medicare Improvement for Patients and Providers Act of 2008 to collect data regarding physician use of advanced diagnostic imaging services.

Today, CMS staff will not be able to respond to your comments, but intend to consider this information obtained as input to develop this demonstration.

As outlined in the Special Open Door Forum announcement, CMS is interested in obtaining feedback in the following areas -- demonstration framework, point of order and point of service systems, and imaging procedures.

I will now turn the call over Ms. Linda Lebovic, who is the CMS Project Officer for this effort.

Linda?

Linda Lebovic: Thank you. Thank you. I apologize for being late, but people in the room can see we're having some technical difficulties with our brand new laptops that are encrypted beyond our capabilities.

But it gives me a chance to introduce to you the CMS team. First let me say thank you for coming out in this rainy weather in - early in the morning.

But it gives us an opportunity to introduce ourselves. As Natalie said, I am Linda Lebovic. I am the project officer for this demonstration project.

My two managers, John Pilotte, who is the division director of the Medicare Demonstration (unintelligible) we're the division of the - what are we, John? The Division of Payment Policy Demonstrations, thank you. Mark Wynn, who is the senior technical advisor for the division, and as you can see, and Linda Magno, who is the group director for the Medicare Demonstrations Program Group in the Office of Research, Development and Information.

We also have Noemi Rudolph, who is the Division Director in our Research and Evaluation Group, also in the Office of Research, Development and Information.

And along with us (unintelligible) is the Lewin Group and we're very honored to have them as our research contractor. And I will let the three colleagues here introduce themselves.

Charlie Bruetman: Good morning. I'm Dr. Charlie Bruetman and I'm from the Lewin Group. I am the project director for the demonstration from the contractor side and I'm a senior vice president at the Lewin Group from for the Federal Health Group.

Sharman Stephens: Hi. I'm Sharman Stephens and I am also in the federal health group at Lewin and I'm the project manager for the demonstration on the Lewin side.

Carol Simon: Good morning. I'm Carol Simon. I'm a vice president at the Lewin Group, also in the federal health area. And I am leading the demonstration design.

Linda Lebovic: Okay, thank you.

Today's agenda is pretty much a demonstration overview. We'll go over the law. And for those of you who are on the telephone line, please know that every - everything that we're talking about is available on the web site, so there is the legislative language posted on the web site and we'll be going through the law.

And we'll be talking about - we'll be going through the questions as Natalie said that we listed and posted on the demonstration - on the Open Door Forum announcement. There are some questions. There were three basic areas -- the demonstration framework, the point of order and point of service systems, and imaging procedures. So we would definitely - we're interested in a lot of information from you, but what we thought would be most productive today would be to focus on those three major topics.

And then we will give you, again, the demonstration web page and email box address for those of you who have not yet discovered that.

So let me first go over the ground rules for today. For folks here, there is a microphone in the center of the room that we would like you to use. We will be allotting about 30 minutes for each of those three topic areas that I just mentioned.

There if a queue for the phone if you would pay attention to our Operator, please.

And please limit your comments to two minutes. This allows everybody to have the opportunity to speak. I think there was over 100 folks on the line. So there is probably about 35 folks here at CMS in the multipurpose room with us today, but there are a lot of other folks who would like to comment I assume, because we would really like to have a discussion.

And then we'd also ask you both in the room and on the phones to identify yourselves and your organization when you start to speak.

Should I pause for the slides or keep going? Keep going. Okay.

The legislative mandate, and, again, as I said, the law is posted on the web site, Section 135(b) and we actually just (abstracted) our section for you so it's easier to make it through the law.

Section 135(b) of the MIPPA is - it sets the parameters for this demonstration. There are requirements that CMS needs to follow and, of course, there are limitations that we need to pay attention to as well.

The goal of the demonstration is to collect data regarding physician use of advanced diagnostic imaging services to determine the appropriateness of services in relation to established criteria and physician peers.

What we need to look at, too, is what impact does the point of service and point of order have on ensuring the patient receives the right test at the right time. So it's important to understand this demonstration isn't about denying services, but, again, ensuring the patient gets the right service at the right time.

So the imaging services that are included in the demonstration are diagnostic magnetic resonance imaging or MRI, computed tomography or CT, nuclear medicine such as PET, and excluded by law is x-ray, ultrasound, and fluoroscopy.

(Unintelligible).

So specifically under Section 135(b)(2), we are required to conduct a two-year demonstration period. We are required to use the appropriateness criteria with emphasis on transparency. Transparency will be very important in the demonstration, as is as you can see today consultation with medical associations, professional organizations, and other stakeholders in advanced medical imaging.

Point of order and point of service systems, we need to understand what is available and current use of these systems currently.

(Unintelligible).

And also provider and beneficiary feedback, we're going to be asking - or you specifically about this as well.

Administrative costs and incentives, again, there are some incentives required by the law.

Okay, I'm on 8. And there it is.

Okay, for those of you on the telephone, what this slide says is the law says no prior authorization shall be used in the demonstration.

Okay, so status is as you've met the Lewin Group here, they have won through a competitive process the design and implementation contract. And we're very delighted to have them as our team. We've really enjoyed working with them thus far.

And we are right now gathering information from stakeholders about issues related to the demonstration, design, and implementation. For instance, this Open Door Forum listening session is a listening session.

We have no design drafted to give to you to critique or to comment on. We're really trying to understand what is currently going on in the advanced imaging community and what the current business models are. And we anticipate that there'll be future teleconference Open Door Forums. But we wanted to do this initial one in person.

So today's focus is the demonstration framework, the point of order and the point of service systems, and the imaging procedures.

The questions for those of you in the room and also on the phone, the questions are specifically outlined in the Open Door Forum announcement starting in the fourth paragraph. And John will be leading the discussion through that.

So let me say thank you very much for coming and for dialing in. And here is John Pilotte.

John Pilotte: Well, thank you, Linda. And, again, welcome to CMS and rest assured we're much better at running demonstrations than we are in dealing with our computer equipment. So don't worry about that.

The first session that we wanted to actually get input and comment on was around the demonstration framework. And, again, we'll have about 30 minutes that we'll give you all an opportunity to comment on in each of these sections, including people here, as well as on the phone.

And we would just ask that in a moment if you're interested in commenting that you go up to the microphone so everyone can hear you, including those that are on the phone. And then we'll queue up the callers.

We actually have a couple of things that we're really interested in looking at in terms of the demonstration design, which is really sort of what we're after here.

And they relate to really sort of how to evaluate the impact of the demonstration, particularly the impact on point of order and point of service systems in - on the effective use of imaging services, particularly in light of the fact that prior authorization, which seems to be sort of the industry

standard, is currently used. And there is sort of a migration to a more sort of decision support at the point of care between the physician and the patient.

So we're interested in really sort of how can this demonstration really be designed to sort of effectively evaluate the impact of using (appropriateness criteria) on the effective use of imaging services.

And there's really sort of a couple of ways that we could look at this in terms that we're interested in sort of some guidance on not only that question, but also then sort of should we be looking at specific geographic areas around the country to really target this demonstration or should we be looking at more of a national initiative that would be open to physicians and others across the country. Should we select specific types of systems to focus on under this demonstration or should we be looking more broadly?

And then really how do we get physician participation in this demonstration? Certainly there are incentives that are called for around administrative costs and participation (unintelligible) performance that are mentioned in the statute, but is that enough to get physicians to participate actively in this?

Are there other opportunities around quality and patient safety that would be equally as attractive and along with the provider feedback on effective imaging use by physicians (unintelligible).

And then really sort of then what are sort of the sites or sort of the organizational structures that we should be looking at? Should we be looking at large groups or integrated delivery systems who may be currently using this type of technology or be on the cusp of making those decisions and putting (unintelligible)...

That's our regional office.

John Pilotte: The - should we be - or should we be looking at perhaps vendors that have these systems that then partner with a provider group or a physician network or some other sort of entity to sort of bring that to the table in terms of sort of a demonstration organization that we could then sort of evaluate.

And then finally sort of what are your thoughts in terms - and views on in terms of sort of should we be looking at randomized control designs under this demonstration or are there other effective sort of evaluation methods that involve comparative groups and so forth to assess the impact.

So that's really kind of what we're after here in this first section and it's sort of the highlights of sort of the three questions that were in the announcement and so forth.

So with that, I would sort of open it up for public comment.

Natalie Highsmith: Okay, David, if you could just remind everyone on how to get into to the queue to ask a question? And folks here in Baltimore, if you have questions or your comments prepared, you can please go ahead and step up to the microphone. We will be taking two questions here from Baltimore, two questions from the phone lines, and alternating that way.

David, if you could just remind everyone, please?

Operator: At this time I would like to remind everyone if you would like to ask a question, please press star and the number 1 on your telephone keypad.

Natalie Highsmith: Okay, let's go ahead and take questions here from Baltimore, any statements here from Baltimore? Please line up at the microphone and please state your name and what organization you are representing today.

Mary Vogel: I'm Mary Vogel, program manager for imaging for CTS Healthcare.

We've analyzed the same question that you asked today regarding the demonstration framework in support of our project for VA/DOD image sharing, as well as civilian settings.

Our recommendations include integrate any functionality or system you introduce into the clinic with the existing workflow. This will help ensure the highest rate of user adoption.

Obtain management support -- in the later stages of your effort, management insistence will be key.

A randomized experiment will allow inferences to be drawn with the highest degree of confidence.

We would also suggest that couple this with the analysis of data in the PAC system. We have codified this information in an effort to transfer image data quickly and analyze it.

Select control and intervention physician groups based on patient load, specialty, age of patients and physicians, as well as the technical environment.

Start small. Choose the most expensive procedures first for a return on your investment.

Conducting a highly visible initial proof of concept will help you pre-sell the effort to get stakeholders accustomed to the model. These early participants will be your onsite champions and have a vested interest in seeing the project succeed.

To solicit physicians' participation, minimize hassle, additional work, and liability. Those showing early interest in the specialties and clinics selected for the study will be key for building a base of support.

Incentives for participation will - should include (unintelligible) certifications and CME requirements. Be sure to consider (unintelligible) funding to offset the burden to the clinics participating. Many of them are stretched with workloads as it is.

Thank you.

Natalie Highsmith: Okay, we'll take another comment from Baltimore.

Don Rucker: Yeah, hi, Don Rucker. I'm Chief Medical Officer for Siemens and we make a lot of the imaging equipment here.

Two methodologic sort of requests for the demonstration -- one is that in these high resolution studies, there are typically a lot of clinical questions being asked of each study.

So, for example, if you're doing a chest CT or not just looking let's say at coronary disease, but you're looking at aortic disease, you're looking at pulmonary vascular disease, you're looking at bone cancer, there are a whole bunch of potential things.

And so that the questions in the study actually reflect the entire differential diagnosis, sort of, you know, the concept of the long tail where you have a lot of low probability things, you know, the Amazon, eBay, Google type of model, because that drives a lot of high resolution imaging requests.

The second sort of methodologic thing is that there's a real value to negative results that I think is often missed in these studies. Because if you have negative result, it means often that you could stop further evaluations. You can stop things like further visits to the ER, you know, you would stop empiric treatment that can go on for years. You get people back to work.

So there's some very tangible things out there and I would just - we would just request that your evaluation process look at the benefit of negative results.

Both of those things I think can be done with some relatively simple questions. You don't need to ask about everything in the differential, but just general questions about did this change decision-making in some other way.

So that's very - those things are very important with high resolution imaging, both of those aspects, and we'd just request that be considered.

Thank you.

Natalie Highsmith: Okay. And David, we'll take two comments from the phone lines.

Operator: At this time, there are no questions in queue, ma'am.

Natalie Highsmith: Okay, we'll go back here to Baltimore.

Robert Hendell: Good morning. My name is Dr. Robert Hendell and I'm here on behalf of the American College of Cardiology.

The American College of Cardiology strongly supports the goals of the Medicare Imaging Demonstration Project.

For the past 25 years, the ACC has produced clinical practice guidelines and more recently developed appropriate use criteria to provide guidance to practitioners, patients, and policymakers regarding for whom and how often cardiovascular imaging and other procedures are performed.

It is well appreciated that cardiovascular imaging services comprise a significant proportion of overall Medicare spending, although the rate of growth has leveled off in recent years, possibly related to the ACC's appropriate use criteria.

These documents were developed to provide physicians, practices, and outside stakeholders parameters to understand and improve practice utilization based on medical evidence and expert opinion. These criteria have direct applicability to clinical situations and they may effectively be implemented to evaluate practice patterns.

We support both the point of service and point of order applications of the appropriate use criteria.

The point of service approach provides bias-free data regarding practice habits as shown in a recent study of more than 6000 patients, which revealed how appropriate use criteria would function in multiple real-world practices.

Patterns of use and potential overuse were identified and methods to improve appropriateness were delineated. We believe that moving towards a point of order system, however, will permit maximum impact on medical decision-making, hence our support for this approach also.

As a result of the American College of Cardiology's experience in the development and implementation of appropriateness criteria, we recommend the following -- cardiovascular imaging be included in the demonstration; encourage medical societies to assist in recruitment and logistical planning; incorporate standardized data elements based on published multi-society documents; develop a uniform data collection instrument for all phases of the demonstration; collect data on all patients in order to standardize workflow; capture the most common indications for inappropriate use; provide incentives for participation by either reduced workload or a financial bonus; develop decision support tools for test appropriateness; distribute reports of appropriateness patterns for quality improvement programs; develop a model in the demonstration that can be scaled to and used by other practices upon completion of the demonstration.

The ACC encourages CMS to include clinical experts and key medical organizations in the design, implementation, and evaluation of the demonstration project so as to ensure the results can be used by the entire healthcare community.

The ACC is ready to assist in any way possible.

Thank you very much.

Natalie Highsmith: Okay, another comment from Baltimore.

Ilyse Schuman: I'm Ilyse Schuman, the Managing Director of the Medical Imaging & Technology Alliance, the collective voice of medical imaging and radiology, radiation therapy equipment manufacturers, innovators, and product developers.

Through MIMA, MITA is also a leading standards development organization for medical imaging equipment. These standards are voluntary guidelines that establish commonly-accepted methods of design, production, testing, and communication for imaging and cancer treatment products.

Sound technical standards of this kind improve safety and foster efficiency in healthcare as delivered. MITA is a strong advocate for the appropriate use of imaging services.

MITA works closely with policymakers and other stakeholders in the medical imaging community, developed the appropriateness criteria provision contained in MIPPA.

These provisions were an important step towards ensuring the proper utilization of medical imaging services.

The medical imaging industry plays a critical role in the successful implementation of the appropriateness demonstration project. The industry is continually working to improve medical imaging technologies to aid in the screening, diagnosis, and treatment.

Therefore, it is imperative in any discussions on the appropriateness of imaging services to ensure that the latest technological advances are included in the discussion.

Advances in imaging technology can alter the appropriateness of a particular diagnostic tool or treatment. MITA members are the only ones able to provide this needed information.

As CMS gathers input on the design and implementation of these provisions, the medical imaging industry is a valued and necessary resource. The expertise of the industry with respect to advanced imaging equipment is a critical component of realizing the legislative intent of ensuring the appropriate use of such services.

MITA and its members offer their expertise and look forward to engaging in a collaborative process for designing and implementing the demonstration project.

Natalie Highsmith: Okay, thank you. Okay, David, let's check the phone lines one more time.

Operator: Your first question comes from the line of Steve Forthuber. Your line is open.

Steve Forthuber: Good morning. My name is Steve Forthuber. I'm with RadNet and we own and operate 175 imaging centers across the country, including 35 here in the state of Maryland.

And I just wanted to reinforce a couple of things. One, I think it was the gentleman from Siemens who made a comment about the overall value of imaging.

And based on our experience dealing with a lot of the RBMs in the different states, we would request that you not look at imaging in a bubble. It is a diagnostic tool that if used appropriately should reduce the overall cost of healthcare.

So we would encourage looking at outcomes of, you know, performing a procedure, compare that to the outcomes of not performing that same procedure for a similar indication and to see what can be learned from that.

We would also as a large provider, you know, volunteer our services or expressed an interest in being involved. We as I said have many centers across multiple states and believe that many of our referring groups would be interested in participating so we may be a resource across a common platform for you.

We would also encourage that as you look at the appropriateness of imaging, you not only focus on uses in - by radiologists, but you look at what's occurring with CT in emergency departments, you look at use from self-referral or multispecialty group sources so that you gain knowledge on the patterns and variances among all of those.

Natalie Highsmith: Thank you. Next comment, please.

Operator: Your next comment comes from the line of (Jeanne Ossavito). Your line is open.

(Jean Acevedo): Hi. Thank you. (Jean Acevedo) with (Acevedo Consulting) in South Florida. We're a medical coding and compliance consulting firm. And this is going to sound like a recurring theme. I was actually going to speak to the CMO of Siemens comment and the gentlemen before me now who has been a great lead-in to my comment.

I had the pleasure of attending the Coalition of State Rheumatology Organizations advocacy conference in Washington, DC at the end of April. Dr. Tom Valuck and as well as Carolyn Clancy both spoke there.

But there was another physician, a nongovernmental physician, who spoke. And he presented data that was just amazing and just supports the last speaker's comment. It was a study done on the prevalence and number of hip fractures compared to the utilization of bone density scans.

And at the same time that bone density became something that the Medicare program not only approved, but encouraged. And studying hospital data, it was very clear that the incidence of hip fractures and hospitalization costs went down precipitously. It was statistically quite significant.

So I, too, would ask that as you move forward with the demonstration that you consider outside the box, not necessarily the obvious utilizations. And I know I come from a part of the country that has a high utilization of some of the high tech imaging procedures. And I'm sure that not all of it is medically necessary, but I think it's really important to make sure that you look at the total picture.

Thank you very much.

Natalie Highsmith: Okay, next comment from the phone lines.

Operator: That's it. At this time, there are no more in queue, ma'am.

Natalie Highsmith: Okay, we have a comment here in Baltimore.

Michael Bettman: My name is Dr. Michael Bettman. I'm representing the American College of Radiology.

We forwarded a statement to you. I want to read part of that to you and then make a couple of additional comments.

The American College of Radiology has seen tremendous growth in the nature and the importance of imaging over the last couple of decades. This has led to dramatic improvements in the patient care. While the increases in use and associated costs have also been impressive (unintelligible) reason for the creation of this demonstration project.

We believe that imaging in some situations may be used or - as used inappropriately and the ACR is committed to improving utilization. We believe that this can be best achieved through clinical research and education, both based on sound information.

To achieve this goal, the ACR has developed the ACR appropriateness criteria. They are based on a clear, transparent, and reproducible methodology and have the aim of guiding the use of imaging in an evidence-based manner.

The ACR appropriateness criteria were begun in 1993 and are regularly updated. They address a broad range of clinical scenarios, common clinical scenarios, with the entry question of if I am considering an imaging study in this clinical setting, which if any should I order?

We believe that the CMS appropriate use of imaging services demonstration projects provide a landmark opportunity to improve the utilization of imaging and we strongly support them.

We believe that using the ACR appropriateness criteria and as well as additional appropriateness criteria as the basis for education and decision-making, particularly in point of order systems, is an important step in achieving both the immediate and long-term goals of these CMS efforts.

I wanted to comment additionally on the specific questions of the demonstration framework. We believe that it should be a national effort rather than regional.

A randomized controlled trial or trials are clearly desirable, but will be exceedingly difficult and have been notoriously difficult to achieve in the imaging world. And therefore we would recommend that these be well organized observational studies.

We also believe that they can be best achieved if they - particularly the intervention or the comparisons are based on use - utilization of a computerized physician order entry system.

And there are CPOE systems that do incorporate appropriateness criteria (unintelligible) ACR appropriateness criteria that are available now, as you know.

Thank you.

Natalie Highsmith: Okay, comment here in Baltimore.

Barbara Rubel: My name is Barbara Rubel and I am President of the Radiology Business Management Association. And on behalf of the RBMA and the nearly 2400 radiology practice managers and other business professionals in radiology,

thank you for this Open Door Forum and the opportunity to speak with you today.

RBMA members are on the front line in dealing with rules and procedures for ordering imaging procedures and services and know first-hand the myriad of issues surrounding process and payment implications.

RBMA believes that CMS's primary goal for this demonstration project should be to improve the process of ordering imaging services that are received by Medicare beneficiaries through an accountable process that is prospective, transparent, consistent, educational, and nonintrusive.

RBMA strongly believes that the goal is best accomplished through a computerized point of order system known as an order entry system.

RBMA highly recommends that any process or methodology be restricted to prospective options only, which supports CMS's goal of the right exam at the right time prior to service delivery.

The imaging order entry system, either point of service or point of order, needs to be transparent, evidence-based, and must utilize appropriateness criteria, such as the ACR's appropriateness criteria previously referenced, to ensure Medicare beneficiaries receive the most appropriate study the first time.

The value of any order entry system will depend largely on the predictability of the system, accuracy of the underlying data, and reliability of comparisons. The imaging order entry system needs to provide constructive and educational feedback to the ordering physician in a real-time format without repercussions

and in a manner that ultimately improves physician ordering behavior, resulting in a decrease of the ordering of inappropriate or unnecessary exams.

The imaging order entry system need not interfere with the ordering physician's medical decision-making, the decision-making of the imaging providers and patients, or interfere with the physician/provider relationship.

I respectfully direct you to the written statement that we have previously submitted and I have a copy here today.

And I thank you for your time and attention.

Natalie Highsmith: Okay, David, do we have any comments from the phone lines?

Operator: Your next comment comes from the line Cally Vinz. Your line is open.

Cally Vinz: Yes, this is Cally Vinz. I'm the Vice President at the clinical - Institute for Clinical Systems Improvement.

And we've going doing an imaging - high tech imaging utilization project for the last four years. And actually pretty much support everything that almost everyone has said at this point.

But through our experience, what we would urge the project to support is point of order decision support. And we would support that mostly because of the shared decision-making that is done then between the patient and the provider.

So, of course, the patient and provider relationship, it allows for collaborative decision-making, as well as provide feedback immediately to the provider so it provides that education almost immediately.

We would urge the support of a common set of appropriateness criteria based on ACR, ACC, the specialty organizations, highly evidence-based appropriateness criteria that capitalize on the use of the MRs where the MR is available and urge that that would be more incented or more highly incented to use the MR, to use decision support at the point order.

And thirdly, we would really strongly support extensive data on the utilization trends that can be drilled down directly to the provider and enabling comparisons between provider group, specialty organizations, organizations with and without imaging equipment, and then allows for the ability to do research on outcomes and the use of imaging and how that use positively impacts patient outcomes in the long run.

So we are really excited for this demonstration project to get underway and anxiously await the - what the model will look like and would be willing to help in any manner with that we can.

Thank you.

Natalie Highsmith: Thank you. Next comment from the phone lines?

Operator: Your next comment comes from the line of Steve Forthuber. Your line is open.

Steve Forthuber: Hi. I had another comment. I was listening to some of the other comments. Again, it's Steve Forthuber from RadNet.

One of the things I wanted to emphasize is ultimately I think in - if you use a prospective system, I would make the radiologist accountable rather than the referring physician.

Again, at least in our experience, what happens with some of these RBMs is they simply wear down the referring physician by putting, you know, so much bureaucracy in place that it's just easier for them not to order the exam.

And if our goal is the appropriate use of this technology so that we provide the proper care, we don't want to discourage use if it's appropriate. So I think ultimately the radiologist is the individual in this process that's trained to be the consultant, the one that should know with an indication which is exam is the right exam.

So I think they are the consultant. They actually have the financial incentive to do the right thing. They're not going to be incented to do procedures that ultimately aren't appropriate and won't be paid for.

So I think I would keep a focus on keeping this in the right hands. I think that makes it more convenient for referring offices that are typically overburdened as it is, particularly the primary care physicians, and they don't need another headache.

I would also say as you get further down the line, rather than involving the RBMs, I think it - again, from our experience it's best if we keep whatever the setup is between the payer, in this case CMS, and the provider and try and work together.

Again, we want the same outcomes. Better to keep the dollars in the system if you will between payer and provider than to bring another middleman in who may not necessarily add value to the process. And I do like the idea that I heard from I think the prior individual, again, focusing on variations.

Don't punish everybody. If you want an incentive out there and there are providers that are doing a great job down the road, I think you want to focus in on variances among providers and work on educating those that - whose statistics may be outside the norm.

Thank you.

Natalie Highsmith: Thank you. Are there any comments here in Baltimore? Okay, we'll go ahead and go back to the phone lines. David?

Operator: Your next comment comes from the line of Ed Eichhorn. Your line is open.

Ed Eichhorn: Good morning. My name is Ed Eichhorn and I'm speaking today on behalf of the American Society of Neuroimaging. We represent neurologists, neurosurgeons, and neuroradiologists who are interested in the advancement of imaging techniques to evaluate the nervous system.

I wanted to just also support the comments that Steve from RadNet made. With respect to the issue of point of order and point of service approval systems, we suggest the emphasis in the study should be on point of service for the initial approval request.

The provider of the imaging service is reimbursed for the technical component and the interpreter for the services is reimbursed for the professional component of the service.

In the current approval systems, as Steve mentioned, radiology business management companies require that physicians who order the study carry the administrative burden and the cost for obtaining the approval for the ordered test without any reimbursement.

We believe that the primary responsibility for this approval should be with the provider of the imaging services and not the ordering physician based on the fact they're being compensated for their services if approved.

As a second point, we also believe that imaging services that are provided on an emergency basis regardless of the place of service, such as the diagnosis of a transient ischemic attack or a minor stroke, should not be subjected to any preapproval process as a part of this demonstration.

Thanks for the opportunity to comment.

Operator: Your next comment comes from the line of Paul Danao. Your line is open.

Paul Danao: Yes, thank you. This is Paul Danao from American Imaging Management. I just had two quick comments based on previous comments that were raised.

First of all, in regards to point of order versus point of service, I would respectfully disagree with the previous two comments that these services should be directed at point of service.

The importance of point of - having these systems focus at the point of order is that the physician that is ordering these services is the one that has the clinical information on the patient.

And it is usually then at that area where you can get the most information that you can do the determination, and as well as the education on the use of the service.

The second quick point is on - a lot has been - several comments have been raised about the importance of automating whatever process using EMR and CPOE.

As you look at that, one thing that I would be interested that should be integrated into the study is given that EMR and CPOE nationally have - still have a low penetration rate, how would the demonstration - the demonstration project should take a look at how anything that is shown on a limited basis would be extrapolated to the broader system that covers Medicare patients.

So thank you very much.

Operator: Your next comment comes from the line of Steven Gould. Your line is open.

Steven Gould: Thank you for allowing me to speak today. I'm Steve Gould, DC, a chiropractic radiologist with the Council on Diagnostic Imaging and the American Chiropractic Association with nearly 70,000 chiropractors in the US seeing neuromusculoskeletal conditions, we would like to be considered for inclusion in the imaging studies.

Currently chiropractors are allowed to participate in the Medicare system through limited diagnoses and limited procedure codes, we provide a physician-level service, that being manipulation.

However, we can not order or interpret imaging through Medicare. Patients must pay out-of-pocket for these procedures when they receive them through our offices.

We would like to be included in the demonstration process in order to confirm our appropriate use of imaging. We have data on non-Medicare patients that currently shows a positive rate of approximately 94% for an MRI center for chiropractic-referred patients. At the same center, there was approximately an 86% positive rate for medically-referred patients.

With such high positive rates for the imaging, we believe that this may indicate that we actually underutilize MRI, at least through the chiropractic providers.

Chiropractors are well positioned by training and scope of practice to aid in health and wellness programs and also as - to alleviate some of the stress of shortages of primary care doctors in order to screen patients prior to referral to specialists.

Ordering MRI and other advanced imaging are important for appropriate diagnosis and - in back pain and other pain syndromes. The chiropractic community has also put together the Council on Chiropractic Guidelines and Practice Parameters.

That's an evidence-based practice guides. And the chapter for low back pain has been finalized and the cervical spine and thoracic spine chapters are currently being reviewed.

And, again, we would encourage the inclusion of chiropractors in the study so that we - as we are important neuromusculoskeletal providers. And our main

incentive I guess for the inclusion would be possible full-scale inclusion in the Medicare system in the future.

Thank you.

Operator: At this time, there are no more questions or comments in queue, ma'am.

Natalie Highsmith: Okay, we have another comment here in Baltimore.

Michael Bettman: This is Michael Bettman again representing the American College of Radiology.

I just wanted to further comment a little bit on who should be involved in the - at the point of decision-making. And I would like to agree with the comments made that it should be at the point of order. It should be the clinician who is ordering the study.

The - that clinician is ultimately the one who needs to be educated, who needs to be able to make the decisions most effectively in the future, and who is in possession of the clinical information that dictates the study - the radiologist doing the study while educated as to the utilization and the utility of the imaging modality is limited in the clinical information that can be provided.

And I think secondly it - this - the entire process needs to be both electronically run since that I believe is the direction that medicine is going in the future.

Also that really facilitates the data collection. And I think further it does - as has been pointed out, it should be based on really very clear, data-driven, evidence-based methodology such as appropriateness criteria that are well

developed and well recognized, and should in a sense be selfless. This should clearly not be a project that is done to further the interests of particular participants or non-participants for that matter. Thank you.

Natalie Highsmith: Another comment here in Baltimore?

Robert Hendell: Yes, this is Dr. Robert Hendell from the ACC.

I concur with the majority of speakers and colleagues that have emphasized the value of the point of order system providing the maximum impact with regards to education and also allowing for the maximum amount of critical information to go weighing into the test.

However, the point of service does provide some valuable information, especially at this point in a demonstration project. Our recently-concluded study of 6000 patients was able to establish ordering practice patterns and demonstrate that very few isolated indications were responsible for what appeared to be overuse and inappropriate utilization.

And I think that aspect of the demonstration may be highly valuable in establishing where the problems may exist in a variety of modalities. So I do think there is some value in the unbiased data prior to ordering, putting a new point of order system into place in order to track practice performance.

Additionally, I would also emphasize that I think one of the goals of the demonstration should also be to look at test layering and serial testing, which are continued problems in medical imaging.

The rapidity of when a test should be performed does need to be examined. It is unlikely that that will be fully addressed in a two-year period, but certainly

it's important to look at whether or not testing needs to be repeated over various intervals and that is obviously a major (cause of expenditures).

Thank you.

Natalie Highsmith: Any further comments here in Baltimore? Okay, David, let's check the phone lines?

Operator: Your next comment comes from the line of Alan Kaye. Your line is open.

Alan Kaye: Yeah, hi. Alan Kaye, a physician in Bridgeport, Connecticut. I would like to address the issue of point of order versus point of service.

Given the incentives and the potential conflicts of interest involved in situations where the physician ordering an examination is also the provider of this procedure, how do you plan to deal with this in your process and analysis? It should be taken into account as there's a significant - a potential for a conflict of interest here. And ignoring it would distort the data.

Operator: Sir, does that conclude your comment?

Alan Kaye: That concludes my comment - my question. There's a question there.

Operator: Thank you, sir.

Your next comment comes from the line of Curt Thorne. Your line is open.

Curt Thorne: Hi. Curt Thorne here with Med Solutions. We're a radiology benefits management company.

As you look at the framing the design, I think you - advice that we would provide is to try to capture all of the relevant utilization for a population and look for geographic diversity of the population in order to capture practice variations that are often seen from one geography to the next.

And (unintelligible) the bias of nearly academic medical centers or practice settings that are not representative of your entire beneficiary population.

When you are evaluating appropriateness, our experience is that you can't always judge appropriateness based on utilization only because the level at which a population may need a certain type of care is, again, is not defined nearly by utilization at the practitioner level.

Finally, as you consider the framing of the design, I'd suggest to you that the - some focus on defining what you mean by point of order and point of service is probably appropriate.

Those are terms that sort of by their nature seem to imply what the definition is, but they're not really terms of art in the business that have definitions that everybody is necessarily talking about the same thing.

Thank you.

Operator: At this time, there are no further questions or comments in queue, ma'am.

Natalie Highsmith: Okay, are there are any other comments here in Baltimore?

John Pilotte: Great. Well, that's actually a good segue way into our next session and actually brings us back up on time as well.

The - thank you very much. I mean, I think that you've raised a number of issues and provided some clarification as well in terms of sort of the direction, so sort of the overall framework for moving forward.

I mean, I think one of the challenges that certainly that you heard from and I think sort of remains as well is sort of how to actively engage physicians in this and sort of what - how can we effectively recruit physicians (unintelligible) not only perhaps the ordering physicians, but also (unintelligible) the performing physicians as well and figuring out sort of the role that both those clinicians play in this demonstration (unintelligible).

This next section is on point of order and point of service systems. And as the last commenter indicated that these - what are these systems and, you know, how do the - where do they exist currently, who uses them, what are the major characteristics of them, are they systems that are used retrospectively or are they used prospectively with - by physicians and with the patients and particularly how do both ordering and performing physicians interact with these systems or do only one or do the other interact with them.

I think, you know, these terms of art we actually didn't come up with them. They were actually in the statute. And actually I thought I might just sort of level the playing field here, actually refer back to actually the statute and sort of read the definitions that are in here.

With respect to a point of service model, it says it's a model described in this paragraph is a model that using electronic or paper intake form that contains a certification by the physician furnishing the imaging service that the data on intake form was confirmed with the Medicare beneficiary before the service was furnished, contains standardized data elements for diagnoses, service ordered, service furnished, and et cetera information determined by the

Secretary in consultation with medical specialty societies and other stakeholders (unintelligible) evaluating the effectiveness of the use of appropriateness criteria and is accessible to physicians participating in the demonstration project under this subsection in a format that allows for the electronic submission of such information.

And certainly that was one of the themes that we heard in the last section about how to standardize electronic collection of this information. And certainly given the volume that we're likely talking about, it would be certainly essential.

The point of order model is a model described in this subparagraph that uses a computerized order entry system that requires the transmittal of relevant supporting information at the time of referral for advanced diagnostic imaging services and provides automated decision-support feedback to the referring physician regarding the appropriateness of furnishing such imaging services and provides for feedback reports in accordance with other provisions under the statute.

So when we talk about these systems and we really sort of look at sort of the - refer back to the statute and sort of to say sort of well, what are the really sort of the elements and the criteria of there point of order and point of service systems that we should be defining for purposes of this demonstration and then what opportunities or systems currently exist out there, who uses them, how widely are they used.

Certainly as one of the earlier commenters talked about, the opportunities and - or also the challenges with IT adoption in the healthcare arena, particularly by physicians and particularly in smaller practices as well, but even in - to the extent that there are large practices out there, they're using this automated

decision support or there are other types of mechanisms that could fulfill that role and provide that same type of point of - interaction at the point of care.

I think, you know, one of the other sort of questions that we're interested in again is sort of are these used - systems used prospectively or are they more retrospective in nature and then particularly how do ordering physicians interact with these systems, what role do performing physicians play with these systems to the extent that (unintelligible) the ordering physician or if they are not the ordering physician, do they have interaction with these systems.

And I think - and then finally, I mean, are there real, you know, what are the real differences between these systems (unintelligible) distinction without a difference or there are real sort of tangible differences between these point of order and point of service systems.

So with that sort of introduction, I'll sort of open it up for the next round of comments on point of order and point of service systems.

Natalie Highsmith: Okay, David, we can go ahead and take questions from the phone lines.

Operator: Your first question comes from the line of Ron Kelly. Your line is open.

Ron Kelly: Yes, Ron Kelly, President and CEO of Medicalis. Thank you for the opportunity to speak to these issues today.

Medicalis is one of the key vendors in this entire area and as such has considerable experience in the development and deployment of these POO and POS systems.

Our customer experience has been very positive to date in reducing inappropriate imaging and showing our customers that they can save money and improve quality where these systems are firstly rich in clinical data and use decision support based on evidence-based medicine and secondly that our designed to be physician-friendly and easy to use.

These system attributes in turn lead to better outcomes for patients and savings for both payers and providers.

Accordingly, we suggest you keep these elements in mind when you design the CMS pilot projects.

In terms of the time and limited resources that the statute provides for, we would suggest that you seriously consider existing projects where you can get quick results for less cost and overlay them over existing POO and POS projects, as there are a number of them in the country.

If you need to do new sites, you can only probably recruit physicians who are positively inclined and predisposed to use IT tools to enhance their workflows.

We also believe CMS should use financial incentives to keep the physicians focused on compliance in these projects.

With respect to John's comments, our experience has clearly been that a POO system is used in the ordering physician's office and a POS system is used at the rendering physician's office.

They are similar in that they use some vetting of the order to determine the appropriateness of the order. The major difference we have found is that in a

POO system, it permits the capture of rich clinical data about the patient directly from the patient or from an integrated EMR or CPOE system. For example, it provides for the ability to capture a patient's symptoms, blood tests, allergy information, and family history.

Both of these systems in our experience are used by both payers and providers as an alternative to RBMs.

With respect to specific imaging procedures, we believe CMS should focus on high impact areas as some of the other speakers have talked to -- CT, MR, nuclear cardiology, and PET.

We believe imaging decision support in any medical management program is really about getting to the right test first for the patient, particularly given the radiation exposure of many procedures.

For example, there are many cases in which ultrasound and x-ray are not helpful and should not be done and other cases where ultrasound is being contemplated and the right test should in fact be CT or MR.

Specific procedures at POS solution should be CT, CT angio, MR, MR angio, MR-spec, cardiology imaging and PET. And with respect to POO solutions, we believe you can include all modalities.

Finally, we believe CMS should deploy decision support for as many procedures for these modalities to obtain the broadest-based set of outcomes as possible.

This will assist CMS in identifying the major problem areas for future considerations.

Thank you.

Operator: Your next comment comes from the line of William Bunnell. Your line is open.

William Bunnell Thank you.

In the current paradigm, I believe the single most factors that compromises not only driving quality of interpretation, but justification for reimbursement is the lack of appropriate clinical history with the order.

So rather than sort out point of order or point of service, maybe the project needs to connect the dots. Unless the demonstration establishes minimum standards for clinical history accompanying requests for service, the focus will need to remain at the point of order for the burden of determination of appropriateness of the study.

Thank you.

Natalie Highsmith: Are there any comments here in Baltimore? Okay, David, we can go back to the phone lines.

Operator: Your next comment or question comes from the line of Cally Vinz. Your line is open.

Cally Vinz: Yeah, sorry, Cally Vinz, the Institute for Clinical Systems Improvement.

And our experience with the point of order and point of service decision support during our 2-1/2 year pilot is that in the end, utilization trends tend to

be quite similar, the difference being that when it's at point of service when the rendering provider is doing the decision support, it doesn't support patient centeredness as well because the patient can show up at the time of the service being rendered to learn that they are going to get something other than what they were expected or the rendering provider has to make a communication back to the patient.

Whereas in the point - when the decision support is at point of order, the - in the - when the patient and the provider are in the room together, they're able to have a collaborative discussion, make a decision.

Our providers are telling us that they really like the ability to be able to show the patient the decision support tool and tell them why it is they're making the decisions (unintelligible) it makes the decision they think more rich and enhances the relationship.

Essentially we've found that the providers appreciated the education at the time they're ordering. And if you have a really strong set of appropriateness criteria, the indications are complete enough that you're able to do good decision-making.

And I think the comment that Ron Kelly made about being able to use decision support, evidence-based - based on evidence-based medicine, strong appropriateness criteria, enhancing the utilization of the electronic decision-making process is very key to the adaptation of the whole decision support process within the clinical flow. So you really have to have it work into the clinical flow.

So I would really encourage that to be included in the demonstration process.

Thank you.

Natalie Highsmith: Thank you. We have a comment here in Baltimore.

Robert Hendell: Robert Hendell, ACC.

I agree with the previous comments, especially regarding the value of the point of order model. It certainly does provide excellent decision support for physicians and overall I believe this is the clear place for where the end product is.

However, not to negate the potential value of point of service, especially in the demonstration, in many practices, especially, for example, in cardiovascular imaging, a rather detailed history is obtained prior to the performance of the procedure, so it does provide ample opportunity to gain clinical information that is relevant, in contrast to point of order, which is sometimes being done not necessarily by the physician provider but by assistants that may not have as much robust information.

Perhaps most importantly, though, is that a point of order is often doing - often directed by the ordering physician who orders low volume procedures. In other words, a specific test or procedure may be ordered rather infrequently and hence the overall impact in understanding patterns and overall practice habits may be diminished, whereas a point of service and the laboratory performance may be able to actually track utilization patterns on a more global basis and try to demonstrate emerging trends as targets for education.

Finally, one last comment, one of the prior speakers mentioned the different procedures in PET such as CT and MR. We also believe that it should be focused not necessarily on the procedure, but on the disease state, that often

there are selection different procedures or tests that may be ordered for a specific entity or disease state and it should not be necessarily all of them or that one test is not preferred perhaps in all settings. And we believe the disease state should mandate what test should be ordered and how frequently.

Natalie Highsmith: Okay, we have another comment here in Baltimore.

Michael Bettman: Michael Bettman again from the ACR.

I would like to second a lot of what Dr. Hendell said. I think that it's going to be important to focus on specific disease states simply because information is not sufficiently developed to judge everything. And I think if everything is included, I think there's a good opportunity for dilution and far less robust information coming out.

In terms of point of order, one speaker on the phone suggested that only limited imaging modalities should be included. I think that the reality is that in many situations there are not clear evidence-driven choices as to what - which is best and two different exams may be equally effective.

And to eliminate some of those exams, I think that also limit the demonstration project and its utility. So I think things such as ultrasound and periscopy should be examined, even if they're not the major focus of the study.

I wanted to make one comment on organization (unintelligible) also I think that there's a real opportunity using computerized order entry and electronic medical records to do very robust observational studies with decision support in one group and no decision support in the other group.

The incentives for participation are somewhat difficult, whether those are financial or simply the availability of a physician of the computerized medical record is I think going to be very difficult to determine and will be necessary. But I think in terms of the randomization in a sense, I think that should be readily doable.

Natalie Highsmith: Okay, thank you. Are there any other comments on the phone lines?

Operator: Your next comment comes from the line of Steve Forthuber. Your line is open.

Steve Forthuber: Hi. It's Steve from RadNet again. And I certainly agree with most everything I'm hearing.

Would comment, certainly we agree, particularly in today's day and age, that we should use as much front-end technology for decision support as possible. But, again, maybe the solution that you ultimately come up with will be more of a hybrid between the point of order and the point of service because I think you're servicing at least two distinct groups, again, from our experience.

You have primary care physicians who at least in our centers order upwards of 50% of the high end or advanced imaging that we perform. These physicians typically are not very knowledgeable or up to date on the high end imaging technology. Again, they're very busy maintaining their own practices.

And as someone else noted, they're using some of this technology infrequently. So I think there you want, again, as much technology to help them, but I believe a more consultative relationship between the primary care physician and the imaging provider is advisable.

I think most physician specialties are more consultative in nature. Imaging or radiology does not tend to be for some reason. But I think there you may need a little bit more of that for education. Then the second group you've got mostly specialty or specialist refers -- neurologists and urologists, oncologists, so on and so forth.

They are very well educated on the technology typically and have a good handle on what is needed. They probably can better adapt to the point of order-type technology and don't need as much consultative interaction. So I think the acknowledgement of that as you go into it, you know, may help decide where to go.

Going back to the incentives, again, with the primary care physicians being as busy as they tend to be, we've found that a lot of those offices do not have updated technology, even updated PCs, to interact with some of our web portal technology.

So the incentives for them might be, you know, providing, you know, some type of money for them to upgrade, you know, PCs to proper technology or have software might help them on whatever system you wind up with.

Thank you.

Operator: Your next comment comes from the line of (Raymond Khorasani). Your line is open.

(Ramin Khorasani): Good morning. I am - my name (Ramin Khorasani). I am a radiologist, a physician at Brigham and Women's Hospital in Boston.

I wanted to share with you a couple of comments about our experience about using a computerized physician order entry-enabled system over the past seven years here at - in our organization in Boston.

And we have shown about a 15% reduction in high cost imaging use compared to our 2005 numbers where previously we were showing about a 10% or 15% growth a year. So we know these systems work.

And I wanted to make some specific comments about adoption and POO - point of order and point of service distinctions that folks are making on the phone, which I agree with most of the comments.

We have been using the very same system both on our point of order and our point of service. So I don't think the distinction is as vividly obvious, at least to us, as it is described over the phone.

In our initial implementations many years back, we started with the very same system in a point of service function so we could capture baseline data on how physicians were using high cost imaging. And it was very easy from then to then extrapolate that to a point of order system because this was all a web-based ordering system.

Our adoption is 100%. We do not perform an exam without use of order entry. And there are over 10,000 orders a week that are going through our systems.

From an adoption perspective, I have to make a couple of comments. The important thing to our referring physicians was the validity of our clinical information.

So we ended up having to include all sources of appropriateness criteria, then working with our colleagues at the ACR, the American cardiology societies that you've heard from, and other published - public domain information that could be embedded in order entry systems.

Of critical importance for our users was not only to present the data on evidence, the evidence that we were presenting to them, but the strength of that evidence, whether that evidence came from a randomized controlled trial, whether that evidence came from an opinion of a radiologist, it was very important to our physicians to know that the source and the strength of that evidence was.

And it was critical for our users to have that content refreshed and updated routinely. And I would suggest that the - that CMS consider and require systems to update clinical information on routine basis for it to be credible with their users.

The ease-of-use consideration for adoption required systems that were embedded in workflow. That was previously mentioned. And this we have done with or without EMR in contra-distinction to the comment made by our colleague on the phone from American Imaging Management.

The folks who do not use EMR can actually log onto our web portal and order exams using the same CPOE and decision support systems that other - others use.

The other important element for adoption was the fact that we had all exams included in our ordering system so that we could approach this from disease-state perspective so that inappropriate MRI is just as important as an

inappropriate x-ray that could result in an inappropriate MRI, so including all modalities would be a consideration that we would highly recommend.

Now from an incentive perspective -- and this is the last comment I would make -- the incentives were really critical for adoption of physicians - or adoption of these systems by physicians.

And the critical element for us was replacing the RBM approach in Boston. So our physicians who didn't want to use our order entry system actually had to use an RBM.

And that increased the adoption of our system magnificently over a period of two to three months because they found this approach much more conducive to their workflow and then to quality of care that they were delivering for their patients.

Now alternatively, one could consider, for example, payments attached to exams or additional payments that are attached to exams that are ordered on order entry systems.

And I think a final comment that I would make is that the distinction between point of service and point of order systems may not be as elaborate as folks believe it - there may be because it - we could just be looking at the very same system, just in different phases of implementation.

Thank you for listening to my comments.

Natalie Highsmith: Okay, are there any other comments here in Baltimore? Okay, we can go back to the phone lines.

Operator: At this time, there are no further questions or comments in queue, ma'am.

John Pilotte: Okay, actually we have a little bit more time for this section. I'd actually like to throw out actually sort of one other question in this realm if we could maybe get some quick comments, particularly the last commenter as well.

And in terms of you mentioned some of these systems are accessible sort of via EHR as well as others have commented as well in terms of sort of via web portals and so forth.

Just a quick follow-up question and sort of clarification, who's actually the end user of such system? Is it the physician, is it a nurse, is it some other member of sort of an office staff? And does that really sort of vary by setting as well? If it's a - is it large physician group, a hospital-based facility or a small practice?

Could both people in Baltimore and on the phone (unintelligible) on that comment on that.

Natalie Highsmith: Okay, we have a question here in Baltimore.

Bob Still: Yes, my name is Bob Still and I'm with Lancaster Radiology Associates in Lancaster, Pennsylvania. And we have an MRI practice as well where we operate seven MRI centers.

And I can speak specifically to that. For us, it would be support staff personnel, especially in a point of order entry system that are working with a referring physician support staff personnel in terms of providing information into a system for order entry.

And currently there aren't many physicians, at least in Lancaster County, that are using electronic medical records. But I know there's incentives to get that system in place.

And once that type of system is in place, then I presume that physicians would be providing that information on criteria and using other appropriateness criteria like the ACR. But for right now, it's most probably a support staff system.

Robert Hendell: Robert Hendell, ACC.

I just wanted to comment on a personal level. I'm a practicing cardiologist with a large 50-person cardiology practice that performs and orders cardiology procedures, especially cardiac imaging.

In our practice, although we've had an EHR for more than 15 years, when it comes to test ordering, it is still performed by the ancillary and support staff, usually by secretaries, sometimes by a nurse practitioners, other times by other medical techs that are ordering the various procedures.

At the other end in our imaging facility, who is collecting the information for various point of service type of data collection, that's usually done by nurse practitioners and exercise physiologists who do sort of the intake information. It is rarely, again, the actual physician that's performing it.

But at the ordering end especially, it is almost always being done by an administrative assistant, in a busy cardiology practice anyway.

Natalie Highsmith: Okay, another comment here in Baltimore.

Don Rucker: Don Rucker, Siemens.

I think one technical thing is that when you do the order entry remotely, there's no real electronic standard to send those orders sort of across practice settings.

So either you have an embedded system, for example, the Medicalis system that Dr. Khorasani has built or (unintelligible) those system, but they're really fully embedded systems that, you know, have a web interface.

They don't really necessarily directly - none of these things directly interface with an EMR sitting out in an office practice. So that technical distinction is worth understanding.

Natalie Highsmith: Okay, any comments from the phone lines?

Operator: Your next comment comes from the line of Ramin Khorasani. Your line is open.

Ramin Khorasani: Yeah, thank you, again. Ramin Khorasani, radiologist at the Brigham and Women's Hospital. And I'm responsible for our quality, safety, and IT programs. Sorry I didn't describe that earlier.

Two comments, one was about the use. About 64% of all of the orders are entered by physicians in our practice across the 10,000 orders that I described on a weekly basis.

The remaining 35% of those orders are entered by ancillary staff. We do not perform those exams unless they are electronically signed using the same system by our physicians.

And that's a change over the last year. And I do have to say that we are a more mature if you like - we have a more mature implementation of these IT systems, so we are so, you know, we are three or four years into the program.

So I think it would be difficult to imagine that on day one on a demonstration project that all exams will be ordered by physicians as the practice is here. But that is absolutely possible and feasible.

The second to my colleague from Siemens, actually all ordering implementation is implemented with various EMRs. It's not a single one. It's embedded with multiple EMRs.

And our practices that do not have EMRs, we have the ordering system available to them so they can order directly in our web interface and that information is then available in our risk impact systems in radiology, just for clarification.

Thank you.

Operator: Your next question comes from the line of Cally Vinz. Your line's open.

Cally Vinz: Hi, this is Cally Vinz again. Sorry so much comment.

But with our experience, if the organizations have an EMR that the physician is doing the ordering, the physician is doing the decision support. When an organization has not embedded an EMR, it does vary.

Sometimes if they're using a web portal, sometimes it's a - the physician, sometimes it's their nurse or even CMS or - so, I mean, a CMA or something

like that will be doing it, even a - somebody like a secretary or assistant, like that.

We do have experience with the multiple EMRs are working on embedding these criteria into their system, so it will be available for them. And we do know independent radiology providers are working to embed the criteria so that they could offer something similar to the web portal where you could order and schedule at the same time. And here in Minnesota, we're seeing both things happening. And so that is what we're trying to move forward with.

The one other comment I'd make is we do see that if we don't have all modalities available and you don't embed it in the clinical flow, the uptake by the provider and the adoption by the providers is much less.

So we experienced that needing to have the decision support embedded in the decision-making - or the decision-making embedded into the clinical flow is really important.

We also would encourage that the providers be making the decision support activity instead of someone else.

Thank you.

Operator: Your next comment comes from the line of (Jean Acevedo). Your line is open.

Jeanne Acevedo: Hi, thank you again.

Just quickly, one, I'd like to commend CMS for asking the question so that you don't go down a path similar to what happened with PECOS where after

the fact CMS has found that physicians don't do their own enrollment so that you might actually get some good adoption, very good.

And then couldn't help but notice a couple of us here listening that sounds like maybe you guys need to get together with Brigham. And with that said, I'll take it offline.

Thank you.

Operator: At this time, there are no further questions or comments in queue.

Natalie Highsmith: Okay, we have another comment here in Baltimore.

Michael Bettman: Michael Bettman again.

I just wanted to make one comment about ordering because I think the demonstration project gives us a tremendous opportunity to look at that, particularly point of order.

It - clearly physicians don't always do the ordering of even complex imaging modalities. And that may be some of the reason for overuse or inappropriate use.

And so this project may, in fact, provide information on how ordering is done or how ordering has improved. And I think that as Dr. Khorasani indicated that can be built into the system requiring that in essence education be brought to bear on the ordering process.

John Pilotte: (Unintelligible) that's actually particularly interested - interesting those last comments in terms of opportunity for educating (unintelligible) overall

ordering process as part of this. That's an interesting idea and sort of an opportunity I think with a demonstration like this.

Thank you very much for all of the comments on point of order and point of service systems. That information is helpful as we sort of work through sort of the systems and sort of how they interface with physicians and how they're currently used in actual practice, so with physicians and patients and others who actually are ordering these tests.

The last, final area is on imaging procedures. We've heard some comments already related to sort of the focus of this. Again, the statute talks about focusing on advanced imaging services, which are diagnostic MRI, CT and nuclear medicine, including PET. It excludes x-ray, ultrasound, and fluoroscopy.

Interestingly, we've heard some comments about including other types of sort of non-focused services as part of the demonstration and perhaps maybe on an informational basis (unintelligible) go back and take a look at that.

This - and - but what the sort of next section we're sort of interested in getting at is sort of what are the procedures that we should be sort of looking at in terms of how to focus this demonstration.

We've heard some people talk about sort of all exams should be included. We should focus on various disease states for all of these services, imaging services.

You know, should we be looking at high volume, high growth imaging services where there is wide variation geographically in their use and that have consensus and clinical guidelines that are established by the societies and

through a sort of consensus process and so forth, or should we be looking at sort of more narrow segments?

Perhaps some earlier questioners raised the idea of looking at perhaps sort of other areas where there might actually be wider variation and perhaps even more less appropriate use of the - those services.

So in terms of, you know, what are the criteria we sort of should be looking at in terms of identifying these procedures and then particularly what modalities and so forth fit into those criteria currently that we could be - look at to focus (unintelligible) focusing and targeting the demonstration or should we be looking at everything.

I guess the flip of that is not necessarily what we should be including, I mean, what - are there specific things that we should be excluding where there aren't consensus guidelines or practice guidelines around (unintelligible).

So think then the other sort of piece of this is sort of what are the, you know, are all of these included procedures incorporated in these point of order and point of service systems?

And then, you know, finally then should these procedures sort of focus on sort of specific types of imaging procedures or, again, procedures that we should specifically exclude from this?

So with that, I'm also going to open it up for public comments, both in the room in Baltimore, as well as on the phone.

Natalie Highsmith: Okay, David, are there any questions or comments in the queue?

Operator: Your first comment comes from the line of Ramin Khorasani. Your line is open.

Ramin Khorasani: Thank you. I am sorry if I am taking inordinate amount of time and I think this will be my last comment.

I think including all imaging examinations have a few benefits. And I think the major benefit in our practice has been the fact that we have been able to position our program to our physicians as a quality program rather than a cost-savings program so that we didn't appear to be focused on high cost imaging.

And it has some practical consequences as well and that is a physician who is trying to do an MRI of low back pain that may not be the most appropriate exam may inadvertently get an x-ray of the lumbar spine in that patient that would be doubly useless in that circumstance potentially.

And that could lead to both radiation exposure and additional imaging that could come from incidental finding that one finds on that lumbar spine x-ray.

Realizing that the optimal goal would be to include all of that, at least for that one purpose, we - you - CMS should consider including that, including all of the modalities.

It will also - including all of the modalities will make it easier for the physicians to adopt the system so that they are not ordering electronically for exam one, two, and three, and for everything else they are using paper. That automation impact is an expectation of the same workflow in practice was a major driver in adoption in our practices.

And I think the third benefit is that as more and more evidence becomes available of time, over the lifetime of the CMS demonstration project, it will always be the opportunity to add that evidence in workflow without having to change the workflow of physicians for each exam over time. Because they know from the beginning that everything is electronic, then you have an opportunity to embed evidence as it becomes available.

Thank you and I'll be happy to answer questions if I could be helpful.

Thank you.

Operator: At this time, there are no further questions or comments in queue.

Natalie Highsmith: Okay, we have comments here in Baltimore.

Barbara Rubel: Barbara Rubel, RMBA. Just a quick comment with respect to the focus on appropriateness criteria and the most appropriate exam at the right time for the right patient, to keep that in focus, certainly a good starting point would be to utilize the criteria that have currently been developed and are already available.

Wanted to make the point that to not confuse higher utilization necessarily with inappropriateness, that procedures such as exploratory surgeries are being replaced by CTs, which results in a higher utilization of CT, but is not necessarily an inappropriate increase in utilization.

Natalie Highsmith: Next comment?

Michael Bettman: I wanted to make a couple of comments. Michael Bettman from the ACR.

In regards to the scope of the demonstration project, I think it's going to be impossible really to make the project meaningful, the projects meaningful if everything is covered.

I think you're going to need to be selective And I think it's possible to be selective by looking at relatively common clinical scenarios and then looking for the availability of good quality guidelines, like appropriateness criteria.

And one of the problems that arises is if it's made too broad, then there's more reliance on relatively limited expert input rather than high quality clinical guidelines. And I think that it would be important to try to avoid that.

And there are - certainly are relatively broad and well proven guidelines available from the ACC and from the ACR.

I think also it's important to look at outcomes. I think utilization alone shouldn't be the endpoint. I think there is a need to look at what is the effect of utilization, what is the effect on hospital length of stay or the resolution of specific illnesses or specific symptoms. I think that's - that will be crucial to further understand and improve the utilization of - the appropriate utilization of the imaging.

Robert Hendell: Robert Hendell, ACC.

Dr. Bettman makes a number of excellent points and some of the prior comments also emphasized this. I think specifically focusing on a specific indications and clinical disease states is really the key to determine how tests are being used and which tests are perhaps appropriate and others are not. Focusing in on specific modality may confuse that issue to some degree.

And the elimination of certain modalities -- and I'll stay with cardiology for a moment -- for the detection of coronary artery disease or evaluation of the overall risk for coronary artery disease, there are a number of different options.

And to isolate one or the other in exclusion of a third perhaps, such as echocardiography, which is an ultrasound-based tests, promotes sort of a steerage phenomenon, which has been well described. If you scrutinize one area, it may bulge out in the other area.

And I think looking at the clinical scenarios and disease states provides a more robust approach in incorporating all of the imaging modalities.

There may be some economy to scale to do that also as the data collection instruments and the forms that are utilized are going to collect similar information based on clinical scenarios more related than the specific indications and that can be tracked.

To that end, especially in cardiovascular disease, the ACC along with ACR and other subspecialty organizations have diligently gone through and defined data standards and data elements that may be used by CMS and the Lewin Group to help to formulate these forms and electronic records to calculate this.

In cardiology, we basically comprise approximately 1/3 of medical imaging. And we're very open to the demonstration project and we hope that some of the common disease states in cardiology would be included in the demonstration.

Natalie Highsmith: Any further comments here in Baltimore? Any further comments on the phone lines?

Operator: Your next comment comes from the line of (Alan Kaye). Your line is open.

Alan Kaye: Yes, thank you. Alan Kaye from - a radiologist from Connecticut.

Dr. Khorasani makes some excellent points with respect to inclusiveness and the importance of inclusiveness. But perhaps for the purpose of the demonstration project, we should restrict it for the reasons cited by Dr. Bettman.

Second point is that, again, to reiterate the comment from before that as long as the point of service is the same as the point of order, you're going to have an inherent distortion of the data. And that needs to be taken into account in the demonstration project.

That's all.

Operator: Your next comment comes from the line of Steve Forthuber. Your line is open.

Steve Forthuber: I would just put another vote in for starting small. I like the idea of focusing on the disease state. I think ultimately that accomplishes the goal of including all of the modalities by the end. I like the idea of including outcomes, which we should be able to do in this day and age.

But I would recommend, again, starting with a smaller focus. Let's not boil the ocean as they say. Get that to work well. And if it works well, then you can expand it. But I think much smarter to start small on a project of this nature. Or start focused, not small.

Thanks again.

Operator: At this time, there are no further questions or comments in queue.

John Pilotte: I guess I would sort of - I appreciate these comments and hearing folks talk about focusing on common, accepted, disease state, starting small, and so forth.

I mean, if I would sort of throw it out there as well, I mean, are there specific areas that we should exclude, where there is sort of less - within - if we were to focus on commonly-accepted clinical guidelines and target it on a smaller basis, I mean, are there are specific areas (unintelligible) if you were to look more broadly, I mean, are there specific areas that we should specifically exclude from this.

Natalie Highsmith: Any comments in the Baltimore area here?

Michael Bettman: I think - this is Michael Bettman.

I think that's a very difficult question to answer. And I think it should be data-driven to as large extent as possible. I don't think you can start out by saying we'll exclude infectious diseases or exclude certain large areas.

I think you need to look at where guidelines are available because if you don't have them, then looking at utilization is really very hard to judge or, you know, probably can not be judged accurately.

And I think if you do try to cover too much, then you end up with probably relatively data-free zones that dictate imaging and then it's not - it's really not

terribly helpful. (Unintelligible) change utilization, but is it actually helping the patients.

So I think that to make - to facilitate the success of the demonstration project, so I think you need to look at really data-driven guidelines as much as possible to dictate areas in which you will be looking to express a bias.

Natalie Highsmith: Any comments on the phone lines?

Operator: There are no comments in queue, ma'am.

Linda Lebovic: Well, on that note, I get the pleasure of welcoming you here and letting you go home early. So thank you very much. We really do appreciate all of your insight, all your input, all your comments, all your help.

And please look for us to be coming back with some more questions. And, again, we will probably do it on a teleconference.

I'm assuming that you all have signed up for the listserv. And we will push out any information using the listserv. Anything about an Open Door Forum will either go through Natalie's Open Door Forum listserv and probably duplicated by the project listserv just to make sure that you do get the word.

So, again, thank you so very much sincerely from both CMS and the Lewin Group.

Natalie Highsmith: And also just wanted to remind everyone to send in their comments to the dedicated email box, which is imagingdemo135b as in boy @cms.hhs.gov. David, can you tell us how many people joined us on the phone lines.

Operator: The high number for the conference was 250.

Natalie Highsmith: Two-fifty. Okay. Thank you, everyone.

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